K000101

FEB 10 2000

510(k) Summary

The 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92

Submitter's Name:	Guidant Corporation Advanced Cardiovascular Systems, Inc.
Submitter's Address:	3200 Lakeside Drive Santa Clara, CA 95052
Telephone:	408-845-4174
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Contact Person:	Kobby Dankwah
Date Prepared:	January 12, 2000
Device Trade Name:	RX VIATRAC™ 14 Peripheral Dilatation Catheter
Device Common Name:	Percutaneous Transluminal Angioplasty Catheter
Device Classification Name:	Dilatation Catheter (LIT)
Predicate Device:	RX VIATRAC™ 14 Peripheral Dilatation Catheter (K983055)

Summary of Substantial Equivalence

The design, materials, manufacturing process, and intended use, features of RX VIATRAC™ 14 Peripheral Dilatation Catheter with the 15 mm, 30 mm, and 40 mm balloon lengths substantially equivalent with regards to these features in the predicate device, the RX VIATRAC™ 14 Peripheral Dilatation Catheter with the 20 mm balloon (K983055).

Device Description:

The RX VIATRAC™ 14 Peripheral Dilatation Catheter is a rapid exchange catheter with an integrated shaft system and an XCELON™ (nylon blend) balloon bonded at the distal end. The shaft has a combination of a single lumen design at the proximal end and a coaxial lumen at the distal end. The proximal lumen provides for inflation of the balloon with contrast medium. The distal lumen permits use of a guide wire to facilitate advancement of the catheter to and through the stenosis to be dilated. The proximal shaft

has a tapered stainless steel mandrel which provides support and flexibility to the shaft and is attached at the proximal end.

The balloon, which has 2 radiopaque markers to aid in positioning the balloon in the stenosis, is designed to provide an expandable segment of know diameter and length at specific pressures.

The proximal end of the catheter has a single arm adaptor that provides access to the inflation lumen. It is designed with a luer-lock fitting for connection with an inflation device.

The RX VIATRAC™ 14 Peripheral Dilatation Catheter is available in 75 cm and 135 cm catheter lengths and with balloon diameters of 4.0, 4.5, 5.0, 5.5, 6.0, 6.5 and 7.0 mm.

On the 135 cm catheter length, there are two proximal shaft markers (95 cm and 105 cm from the distal tip). On the 75 cm catheter length, there is a single proximal marker (55 cm from the distal tip). Both indicate the relative position of the catheter to the end of a brachial, femoral or renal guiding catheter. An additional marker is located at the guide wire exit notch and aids in locating the guide wire exit notch

The RX VIATRAC™ 14 Peripheral Dilatation Catheter is indicated for dilatation of stenoses in the peripheral vasculature (iliac, femoral, ilio-femoral, popliteal, infra-popliteal and renal arteries) and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. In addition, the RX VIATRAC™ 14 Peripheral Dilatation Catheter is indicated for balloon dilatation of the PALMAZ™ P204 stent with the 20 mm balloon length only, implanted in vessels ranging from 4.0 mm to 7.0 mm.

Comparison of the RX VIATRAC™ 14 Peripheral Dilatation Catheter (15 mm, 30 mm and 40 mm lengths) to the predicate device, the RX VIATRAC™ 14 Peripheral Dilatation Catheter (K983055, 510k cleared December 30, 1998) indicates that they are substantially equivalent to the predicate with regard to the intended use, materials and design.

Intended Use:

The RX VIATRAC™ 14 Peripheral Dilatation Catheter is indicated:

- To dilate of stenosis in the peripheral vasculature (iliac, femoral, ilio-femoral, popliteal, infra-popliteal and renal arteries) and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

- For post-stent dilatation of the PALMAZ™ P204 stent with the 20 mm balloon only, implanted in vessels 4.0 mm to 7.0 mm in diameter.

It is not intended for use in the coronary vasculature.

Technological Characteristics:

The RX VIATRAC™ 14 Peripheral Dilatation Catheter (20 mm length) is a Percutaneous Transluminal Angioplasty Catheter. It is comprised of an integrated shaft system and a balloon near the distal tip. The shaft has a combination of single lumen and dual lumen tubing. One lumen is used for inflation of the balloon with contrast medium. The second lumen in the distal shaft permits the use of a guide wire to facilitate the advancement of the catheter to and through the stenosis to be dilated.

Similarly, the RX VIATRAC™ 14 Peripheral Dilatation Catheter with the balloon with 15 mm, 30 mm, 40 mm balloon lengths are identical with the exception of the balloon length. Both the proposed and predicate devices are for single use only and are PTA Catheters.

Performance Data:

In vitro bench testing was performed to demonstrate that the RX VIATRAC™ 14 Peripheral Dilatation Catheter met the acceptance criteria and performed similar to the predicate devices. The functional tests met product specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 10 2000

Mr. Kobby Dankwah
Guidant Corporation
Vascular Intervention Group
3200 Lakeside Drive
Santa Clara, CA 95054

Re: K000101
The RX VIATRAC™ 14 Peripheral Dilatation Catheter
Regulatory Class: II (two)
Product Code: LIT
Dated: January 12, 2000
Received: January 13, 2000

Dear Mr. Dankwah:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known)

Device Name The RX VIATRAC™ 14 Peripheral Dilatation Catheter

Indications for Use The RX VIATRAC™ 14 Peripheral Dilatation Catheter is indicated:

- To dilate of stenosis in the peripheral vasculature (iliac, femoral, ilio-femoral, popliteal, infra-popliteal and renal arteries) and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.
- For post-stent dilatation of the PALMAZ™ P204 stent with the 20 mm balloon only, implanted in vessels 4.0 mm to 7.0 mm in diameter.

It is not intended for use in the coronary vasculature.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

Christopher M. Ahn for Witten